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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference PRD 2004-PCT		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/11329	International filing date (day/month/year) 13.10.2003	Priority date (day/month/year) 15.10.2002
International Patent Classification (IPC) or both national classification and IPC A61B5/03		
Applicant JANSSEN PHARMACEUTICA N.V. ET AL.		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 6 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of 2 sheets.

- This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 25.03.2004	Date of completion of this report 16.09.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Gaillard, A Telephone No. +49 89 2399-7474 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/EP 03/11329

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-18 as originally filed

Claims, Numbers

1-14 received on 02.08.2004 with letter of 02.08.2004

Drawings, Sheets

1/14-14/14 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-8,14

because:

☒ the said international application, or the said claims Nos. 1-8,14 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 1-8,14

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	9-13
	No: Claims	
Inventive step (IS)	Yes: Claims	9-13
	No: Claims	
Industrial applicability (IA)	Yes: Claims	
	No: Claims	1-8,14

2. Citations and explanations

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see separate sheet

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International application No. PCT/EP03/11329

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

III.1 Claims 1-8, 14

No Search Report has been established in respect of claims 1-8, 14 accordingly to Article 34(4)(a)(i) PCT for the following reasons that said claims define, as subject matter, an animal model in which said animal visceral pain will be deliberately generated through a special technical feature. Such special technical feature appears to be contrary to morality.

Therefore no examination of claims 1-8, 14 is performed in view of Article 34.4(a)(i) PCT.

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: US-A-5 275 169 (AFROMOWITZ MARTIN A ET AL) 4 January 1994 (1994-01-04)

D2: US-B1-6 231 516 (CIMOCHOWSKI GEORGE E ET AL) 15 May 2001 (2001-05-15)

V.1 Independent claim 9

The document D1 (fig. 2A) is regarded as being the closest prior art to the subject-matter of independent device claim 9, and discloses (the references in parentheses applying to this document) a balloon catheter having a tubing (40) and a balloon (42).

The subject-matter of claim 9 differs from this known D1 in that fixation means are positioned proximal to the tube end.

The subject-matter of claim 9 is therefore new (Article 33(2) PCT) and appears to acknowledge an inventive ingenuity (Article 33(3) PCT).

V.2 Dependent claims 10-13

Claims 10-13 are dependent on claim 9 and as such also meet the requirements of the

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PCT with respect to novelty and inventive step.

Claim 10 lacks clarity because the wording "is implanted in the duodenum of the test animal" is not contained in the subject-matter for which protection is sought.